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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/986,535	11/09/2001	Nobunao Ikewaki	215051US0	5778

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EXAMINER

LEWIS, PATRICK T

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 10/16/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

<p align="center">Office Action Summary</p>	Application No. 09/986,535	Applicant(s) IKEWAKI ET AL.	
	Examiner Patrick T. Lewis	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3 and 5-23 is/are pending in the application.
- 4a) Of the above claim(s) 16-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,5-15,22 and 23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I in Paper No. 7 dated December 16, 2002, is acknowledged.
2. Claim 16-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 7 dated December 16, 2002. The restriction requirement was made final in Paper No. 8, dated March 21, 2003.
3. Newly submitted claim 21 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Newly submitted claim 21 is independent and distinct from the invention of Group I. Claim 21 is drawn to a method for removing microbes from a body surface. The methodological steps of newly submitted claim 21 do not render does not render obvious the invention of Group I. The examination of claim 21 would require further search considerations, and would indeed impose an undue burden upon the examiner in charge of this application.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 21 withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Applicant's Response dated June 23, 2003

4. In the Response filed June 23, 2003, claims 1, 3, 5, 7, and 9-21 were amended; claims 2 and 4 were canceled; and claims 21-23 were added. Applicant presented arguments directed to the rejection of claims 1, 3, and 5-15 under 35 U.S.C. 102(b) and the rejection of claims 1-4 under 35 U.S.C. 103(a). Claims 1, 3, and 5-23 are pending. Claims 16-21 are drawn to a nonelected invention. An action on the merits of claims 1, 3, 5-15, and 22-23 is contained herein below.

5. The objections to the specification and claims 1-15 have been rendered moot in view of applicant's response dated June 23, 2003.

6. The rejection of claims 1-2 under 35 U.S.C. 101 has been rendered moot in view of applicant's response dated June 23, 2003.

7. The rejection of claims 1, 3, and 5-7 under 35 U.S.C. 102(b) as being anticipated by Hamada, Agric. Biol. Chem., 1983, 47 (6), 1167-1172 (Hamada) is maintained for the reasons of record set forth in the Office Action dated March 21, 2003.

8. The rejection of claims 1, 3, 5-6 and 8-12 under 35 U.S.C. 102(b) as being anticipated by Watanabe et al. JP 06-340701 A (Watanabe) is maintained for the reasons of record set forth in the Office Action dated March 21, 2003.

9. The rejection of claims 1, 3, 5-6, 8, and 13 under 35 U.S.C. 102(b) as being anticipated by Shinohara et al. JP 62-205008 A (Shinohara) is maintained for the reasons of record set forth in the Office Action dated March 21, 2003.

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10. The rejection of claims 1, 3, 5-6, 8, and 14-15 under 35 U.S.C. 102(b) as being anticipated by Hasegawa et al. JP 06-146036 A (Hasegawa) is maintained for the reasons of record set forth in the Office Action dated March 21, 2003.

11. The rejection of claims 1 and 3 under 35 U.S.C § 103(a), is maintained for the reasons of record set forth in the Office Action dated March 21, 2003.

Objections/Rejections Set For the in Office Action dated March 21, 2003

12. Claims 1, 3, and 5-7 were rejected under 35 U.S.C. 102(b) as being anticipated by Hamada, Agric. Biol. Chem., 1983, 47 (6), 1167-1172 (Hamada).

13. Claims 1, 3, 5-6 and 8-12 were rejected under 35 U.S.C. 102(b) as being anticipated by Watanabe et al. JP 06-340701 A (Watanabe).

14. Claims 1, 3, 5-6, 8, and 13 were rejected under 35 U.S.C. 102(b) as being anticipated by Shinohara et al. JP 62-205008 A (Shinohara).

15. Claims 1, 3, 5-6, 8, and 14-15 were rejected under 35 U.S.C. 102(b) as being anticipated by Hasegawa et al. JP 06-146036 A (Hasegawa).

16. Claims 1-4 were rejected under 35 U.S.C. 103(a) as being unpatentable over Watanabe et al. JP 06-340701 A (Watanabe) in view of Finkelman et al., Canadian Journal of Microbiology, 1987, 33 (2), 123-127 (Finkelman).

Response to Arguments

17. Applicant's arguments filed June 23, 2003 have been fully considered but they are not persuasive.

Applicant argues: 1) the art of record does not teach that the glucan is produced by strain FERM P-18099; and 2) the examiner has failed to establish equivalence as a rationale for supporting an obviousness rejection. In response to applicant's assertion that the examiner has failed to establish a *prima facie* case of obviousness, the examiner respectfully disagrees.

The source of β -1,3-glucans as instantly claimed is not seen to result in a patentably distinguishable chemical structure. Applicant's suggestion that glucans obtained from different strains of *Aureobasidium* are not equivalent is noted; however, applicant has failed to particularly point out and distinctly claim the subject matter which applicant regards as the invention in such a way as to obviate the rejection of record. The asserted characteristics differentiating the instantly claimed β -1,3-glucans from other strains of *Aureobasidium* is not recited in the claims. Since the Office does not have the facilities for preparing the claimed materials and comparing when with prior art inventions, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980).

Claim Rejections - 35 USC § 103

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

19. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

20. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

21. Claims 22-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Watanabe et al. JP 06-340701 A (Watanabe).

Claims 22-23 are drawn to a product comprising β 1,3-1,6 glucan.

Watanabe teaches that β -glucans can be obtained by inoculating *Aureiobasidium pullulans* IFO 4466 strain on a liquid medium. See Abstract. In the Figure with the Abstract, Watanabe teaches that the β -glucans are 1,3-1,6-glucans. Finally, Watanabe discloses that the β -glucans can be used in medicines, i.e. pharmaceutical

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compositions, and food additives, i.e. food products, by adding an organic solvent to the culture solution of *Aureobasidium pullulans* IFO 4466 strain.

It would have been obvious to one of ordinary skill in the art to use any strain of *Aureobasidium* to obtain b-1,3-1,6-glucans, as it was well known, at the time the invention was made, that b-1,3-1,6-glucans are available in large quantities in *Aureobasidium*. Therefore a skilled artisan would have been motivated and had a reasonable expectation of success of obtaining b-1,3-1,6-glucans from any strain of *Aureobasidium*, such as the strain of the present invention, FERM P-18099.

Conclusion

22. Claims 1, 3, and 5-23 are pending. Claims 16-21 are drawn to a nonelected invention. Claims 1, 3, 5-15, and 22-23 are rejected. No claims are allowed.

23. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick T. Lewis whose telephone number is 703-305-4043. The examiner can normally be reached on M-F 8:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 703-308-4624. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Patrick T. Lewis, PhD
Examiner
Art Unit 1623



James O. Wilson
Supervisory Patent Examiner
Technology Center 1600

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October 14, 2003